

## **REMARKS**

Claims 1-14 are pending in the application.

The Examiner has rejected claim 1 as being anticipated over the disclosure of United States Patent No. 4,158,895 of Reswick et al. (“Reswick”) and claims 2-14 as being rendered obvious by Reswick.

### **Rejection Under 35 U.S.C. § 102(b):**

The Examiner has rejected claim 1 as anticipated by the disclosure of Reswick, asserting that Reswick teaches a coupling for use in an apparatus for connecting prosthesis to the bone of a stump of amputated limb. According to the Examiner, the Reswick apparatus includes a tubular femoral socket (element 16) having an open lower end adapted to be inserted within the intramedullary cavity of the bone. Reswick also teaches a sleeve (element 20) that is carried below the socket. The Examiner characterizes the sleeve as being a “spacer/bush” and states that the sleeve’s purpose is to provide a compatible interface between the implanted socket and the skin line. The Examiner contends that the sleeve widens out significantly from the end facing the extracorporeal direction to the end facing the intracorporeal direction and comprises a smooth surface. An internal annular groove (element 26) is provided from receiving balls(element 28) carried with a lock pin (element 30) for securing prosthesis (element 32) to the stump (element 10). The Examiner asserts that the Reswick configuration would necessarily provide a seal in the intracorporeal direction between the annular groove and the balls of the locking pin.

### **Rejection Under 35 U.S.C. § 103(a):**

The Examiner has rejected claims 2-14 under 35 U.S.C §103 as being obvious over Reswick. To support the rejection, the Examiner relies upon the analysis provided above, with respect to Claim 1. In addition, the Examiner contends that Reswick also teaches a locking pin (element 30) which is shown to be configured to reach inside the sleeve (element 20) and to be seated in an “interference fit”. The Examiner asserts that the locking pin is necessarily capable of being removable, if provided with proper tools. Further, the Examiner contends that Reswick depicts the locking pin as comprising a length so that it is situated with its distal front edge on a shoulder, which is formed on the extracorporeal device. However, the Examiner acknowledges that Reswick does not explicitly teach the claimed length ratio of the widening bush or specific

materials used to form the components of the device. To remedy the deficiency, the Examiner asserts that it would have been obvious to determine this ratio through routine experimentation, particularly in the absence of any disclosed criticality for the claimed ratio, in order to obtain the desired coupling strength and ease of connection.

The Examiner also characterizes Reswick as teaching that the use of any suitable bio-compatible conventional material for the purpose of providing a compatible interface between the implanted socket and the skin line. Thus, the Examiner reasons that Reswick discloses the claimed invention, except for the adaptation tube or bush being made from or coated with silver, titanium, silver-plating, hydroxyapatite, calcium phosphate, plasma titanium spray, polyurethane, or materials with an antibacterial effect. However, the Examiner states that it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the use of these materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

#### **Disclosure of Reswick:**

Reswick teaches a coupling for use in an apparatus for connecting a prosthesis to a bone stump on an amputated limb that permits a bio-compatible carbon sleeve forming a part of the prosthesis connector to float. The coupling includes a flexible member that is inserted within an intermedullary cavity of the bone and the sleeve. A lock pin is carried by the prosthesis and has a stem portion which is adapted to be coaxially disposed and slidably disposed within the tubular female socket for securing the prosthesis to the stump. The skin around the carbon sleeve is able to move as a result of the flexing coupling so as to reduce stresses caused by changes in the stump shape and/or movement between the bone and flesh portion of the stump.

Reswick is silent with respect to the texture of the outer surface of the sleeve

Reswick as applied by the Examiner does not teach or suggest all elements of the invention and therefore does not anticipate it. As is recited in the claims, the invention includes a spacer that is sealed in the intracorporal direction and which is embodied by a rigid bush that widens out significantly from the end facing the extracorporal direction to the end facing the intracorporal direction and comprises a smooth surface. The seal of the claims is formed between the spacer and the soft tissues by atrophy of the soft tissues onto the bush. By virtue of the design of the bush, the a significantly greater seal is formed in the area of the bush that faces the intracorporal direction than at the interface of the part of the bush that faces the extracorporal direction. Accordingly, the inventive design element permits constant and consistent increase of the seal from a part of the bush facing in the extracorporal direction to the part facing the intracorporal direction. *See*, paragraph [0006]. In contrast, the Examiner interprets Reswick as disclosing a seal formed by the insertion of the locking pin (30) into the female socket (16) including an internal annular groove (26) and locking the receiving balls (28) into the annual groove (26).

Accordingly, Reswick does not anticipate the invention. Similarly, because all of the elements are not present in Reswick, the modifications suggested by the Examiner do not remedy the deficiency. Accordingly, Reswick does not render the claimed invention obvious, at least because all elements of the claims 2-14 are not taught or suggested by Reswick.

### **CONCLUSION**

In view of the foregoing, it is respectfully submitted that the applicant has distinguished over all of the cited prior art. Reconsideration and allowance of the claims at the earliest opportunity is respectfully solicited.

Respectfully submitted,

HANS GRUNDEI

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By: //kristyneabullock//

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KRISTYNE A BULLOCK  
Registration No. 42,371  
FLASTER/GREENBERG P.C.  
4 Penn Center  
1600 John F. Kennedy Blvd.  
Philadelphia, PA 19103  
Telephone: 215-279-9910  
Kristyne.bullock@flastergreenberg.com